

APPENDIX E

SELECTED REFERENCES

Human Subjects Protection

DoD Directive 3216.2, protection of human subjects and adherence to ethical standards in DoD-supported research.

DoD Directive 6000.8, Funding and Administration of Clinical Investigation Programs.

DoD Instruction 1100.13, Surveys of DoD Personnel.

Title 21 Code of Federal Regulation (CFR) 50, 56, 312, 314, Good Clinical Practice (Protection of human subjects; Institutional Review Boards; Investigational new drug application; Applications for FDA approval to market a new drug).

Title 32 CFR 219, Human Subjects Protection.

Title 45 CFR 46, Subparts A, B, C, and D, Protection of Human subjects.

Title 5 U.S. Code 5536, Extra pay for extra services prohibited.

Title 10 U.S. Code 980, Limitation on use of humans as experimental subjects.

Title 24 U.S. Code 30, Payments to donors of blood for persons undergoing treatment at Government expense.

Health Affairs Policy 97-033, 3 Mar 1997, "Policy For External Peer Review For Defense Health Program Extramural Medical Research Involving Human Subjects".

Air Force Regulations

AFI 40-402, 1 Sep 2000, Clinical Investigation and Human Test Subjects in the Medical Service.

Army Regulations

AR 40-38, Clinical Investigation Programs.

AR 70-25, Use of volunteers as subjects of research.

Navy Regulations

SECNAV INST 3900.39B, 27 Feb 1984, Protection of Human Subjects.

NAVMEDRSCHCEN INST 3900.6a.

Non-human Animal Subjects

NIH Publication No. 86-23, Guide for the Care and Use of Laboratory Animals.

DoD Directive 3216.1, The Use of Animals in DoD Programs.

Title 9 CFR, Chapter 1, Subchapter A (Animal Welfare), Parts 1-4.

Access these documents online through http://www.usuhs.mil/tsnrrp/links/management.html
